REMARKS

Claims 1, 3-14, 16, 17, and 39-60 were pending in the present application. Claims 1, 3-14, 16, 17, and 39-60 were rejected. By virtue of this response, claims 1, 3-14, 16, 17, and 40-60 have been cancelled, claim 39 has been amended, and new claims 61-83 have been added. Accordingly, claims 39 and 61-83 are currently under consideration.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and, moreover, have not acquiesced to any rejections and/or objections made by the Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part, and/or divisional applications.

Interview Summary

An in-person interview with Examiner Ewoldt was held on January 23, 2008. In addition to Examiner Ewoldt and Alicia Hager (the undersigned), Catherine Polizzi and Matthew Linnik participated in the interview. Applicant and his representatives would again like to thank Examiner Ewoldt for the courtesy of the interview.

The primary subject of the interview was the Final Office Action dated October 12, 2007. Claims discussed included claim 39. Possible responses to the rejections were proposed and discussed.

In addition, the Examiner's decision not to consider certain documents submitted with the Supplemental Information Disclosure Statement filed on July 30, 2007 was briefly discussed.

Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement is filed herewith. The Examiner's consideration of the submitted references is requested.

As discussed during the interview of January 23, 2008, Applicants note that the Examiner declined to consider certain documents (i.e., Cite Nos. 22, 55, and 70-75) submitted with the Supplemental Information Disclosure Statement filed on July 30, 2007. Applicants do not believe the documents were improperly submitted or cited. Per the Examiner's suggestion in the interview, however, the October 13, 2004 letter from the Food and Drug Administration (Cite No. 22 of the Form SB/08 filed on July 30, 2007) has been resubmitted with the Supplemental Information Disclosure Statement filed herewith along with an identification of the author of the letter, Robert Temple. In addition, the La Jolla Pharmaceutical Co. November 14, 2005 press release (Cite No. 55) which was previously submitted in the July 30, 2007 Supplemental Information Disclosure Statement has been resubmitted with the Supplemental Information Disclosure Statement submitted herewith. In the previous submission, a portion of the citation of the press release as Cite No. 55 was on one page of the submitted form and a portion on the next. As a result, the Examiner mistakenly marked the second portion of the press release as having "no date." Applicants respectfully request consideration of the previously submitted references.

Amendments to the Claims

Claims 1, 3-14, 16, 17, and 40-60 have been cancelled, claim 39 has been amended, and new claims 61-83 have been added. No new matter is added.

Claim 39 has been amended to be directed to a method of stabilizing or improving the health-related quality of life of a human individual with systemic lupus erythematosus (SLE) which involves assessment and selection. More particularly, the method of claim 39, as amended, comprises the steps of: (a) assessing the health-related quality of life of the human individual with SLE; (b) selecting the individual to receive treatment based on the individual's need for a stabilized or improved health-related quality of life; and (c) administering to the selected individual an amount of a dsDNA epitope, which specifically binds to an anti-dsDNA antibody, wherein the amount administered is an amount effective to stabilize or improve the health-related quality of life of the selected individual, and wherein administration of the dsDNA epitope results in a sustained reduction of at least about 10% in the level of circulating anti-dsDNA antibodies in the individual

that is maintained for at least about one month. Support for the amendments made to claim 39 are found throughout the specification as filed and in originally filed claim 39. In particular, support for the newly added step of "(a) assessing the health-related quality of life of a human individual with SLE" is found, e.g., at paragraphs [0155]-[0157], [0164], [0165], [0195], [0202], [0086], and [0190]. Support for "sustained reduction of at least about 10%" is found, e.g., at paragraphs [0084] and [0134].

Support for new claims 61-83 is found throughout the application as filed and as indicated in the following table:

NEW CLAIM(S)	EXEMPLARY SUPPORT
61, 63, 65, 67, 74	Paragraphs [203], [0149]-[0154], [028]
62, 64, 66	Original claim 39, paragraphs [0023], [0155]-[0157], [0164]-[0165], [0195], [0202], [0086], [0190], [0092], [0134], and [0084]
68	Paragraphs [0013] and [0231]-[0232] with sequence corrections supported by paragraphs [0277] and [0066] as previously described at page 22 of Amendment filed July 30, 2007
69, 70	Paragraph [0246]
71	Paragraph [0277]
72, 73	Paragraph [0219]
75, 82	Paragraphs [0121] and [0129]
76, 77	Paragraphs [0027], [0134], and [0084]
78, 79, 80	Paragraphs [0134] and [0084]
81	Paragraph [0160]
83	Original claim 39, paragraphs [0023], [0155]-[0157], [0164], [0165] [0195], [0202], [0086], [0190], [0092], and [0277]

Claim Rejections under 35 U.S.C. § 102(b)

Claims 1, 3-14, 16, 17, and 39-60 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by WO 01/41813.

Applicants respectfully traverse this rejection.

Without acquiescing to the rejection and solely in the interest of expediting prosecution, Applicants have cancelled claims 1, 3-14, 16, 17, and 40-60 and have amended claim 39. The rejection of the cancelled claims is considered moot and Applicants will therefore focus on points of distinction with respect to claim 39 as amended and with respect to the new claims. However, Applicants note that points of patentable distinction also apply with respect to the cancelled claims and claim 39 prior to the present amendment.

WO 01/41813 fails to anticipate (or render obvious) amended independent claim 39, as well as new independent claims 62, 64, 66, and 83 because it does not teach or suggest a method of stabilizing, let alone improving, the health-related quality of life of a human individual with SLE comprising a step of assessing the health-related quality of life of the human individual (or assessing stabilization or improvement in the health-related quality of life of the individual). WO 01/41813 further fails to anticipate (or render obvious) amended independent claim 39 (as well as new claim 83) because WO 01/41813 does not teach or suggest a method of stabilizing or improving the health-related quality of life comprising a step of selecting an individual for treatment with a dsDNA epitope based on the individual's need for a stabilized or improved health-related quality of life. Likewise, the reference does not teach or suggest a method of stabilizing or improving the health-related quality of life comprising a step of selecting an individual for treatment with a dsDNA epitope based on the individual's health-related quality of life (claim 62) or the individual's stabilization or improvement in health-related quality of life (claim 64). The cited reference also does not teach or suggest a method of stabilizing or improving the health-related quality of life comprising a step of selecting an individual for treatment with an adjusted dosage of a dsDNA epitope based on the individual's health-related quality of life (claim 66).

In addition, WO 01/41813 does not teach or suggest the above-indicated methods of stabilizing or improving health-related quality of life involving sustained reductions of at least about 10% in the level of circulating anti-dsDNA antibodies (claims 39, 62, 64, 66, and 83), as well as sustained reductions of at least about 20% or 30% below baseline (claims 76 and 77).

Furthermore, WO 01/41813 does not anticipate (or render obvious) the above-indicated methods where the stabilization or improvement of health-related quality of life is a stabilization or improvement in one or more aspects of health-related quality of life selected from the group consisting of limitations in physical activities because of health problems, limitations in social functioning because of physical or emotional problems, limitations in work or other usual activities because of physical health problems, bodily pain, general mental health, limitations in work or other usual activities because of emotional problems, vitality, and general health perception (claims 61, 63, 65, and 67).

In view of the foregoing remarks, Applicants respectfully request that the Examiner withdraw the rejection under U.S.C. § 102(b) over WO 01/41813 and that the rejection not be applied to the amended claim 39 or the newly-presented or amended claims.

Double Patenting

1. U.S. Patent No. 7,081,242

Claims 1, 3-14, 16, 17, and 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting for allegedly being unpatentable over claims 1-64 of U.S. Patent No. 7,081,242.

Applicants respectfully traverse this rejection.

Without acquiescing to the rejection and solely in the interest of expediting prosecution, Applicants have cancelled claims 1, 3-14, 16, 17, and 40-60 and amended claim 39. The rejection

of the cancelled claims is considered moot and Applicants will therefore focus on points of distinction with respect to claim 39 as amended and with respect to the new claims. However, Applicants note that points of patentable distinction also apply with respect to the cancelled claims and claim 39 prior to the present amendment.

With respect to amended claim 39 and the newly added claims, Applicants submit that the claims are not obvious over claims 1-64 of U.S. Patent No. 7,081,242. Claims 1-64 of U.S. Patent No. 7,081,242 do not contain the slightest hint or suggestion that the conjugates recited in the claims can be used to effect stabilization or improvement in the health-related quality of life of a human individual with SLE or that there would be any reason to assess the health-related quality of life of the individual and select the individual for treatment with the conjugates or an adjusted dosage of the conjugates based on the individual's need for stabilization or improvement in health-related quality of life (claims 39 and 83), based on the individual's health-related quality of life (claim 62 and 66), or based on the stabilization or improvement in the individual's health-related quality of life (claim 64).

In view of the foregoing remarks, Applicants respectfully request withdrawal of the rejection and that the rejection not be applied to the newly added or amended claims.

2. *U.S. Patent Application Nos. 10/814,555, 11/081,309, 11/347,426, 11/373,699, 11/565,467, 11/613,987, and 11/562,174*

Claims 1, 3-14, 16, 17, and 39-60 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting for allegedly being unpatentable over claims 1-26 of U.S. Patent Application No. 10/814,555, over claims 1-39 of U.S. Patent Application No. 11/081,309, over claims 1-27 of U.S. Patent Application No. 11/347,426, over claims 1-21 and 34-55 of U.S. Patent Application No. 11/373,699, over claims 1-26 of U.S. Patent Application No. 11/565,467, over claims 1-21 and 34-55 of U.S. Patent Application No. 11/613,987, and over claims 1-39 of U.S. Patent Application No. 11/562,174.

Applicants respectfully traverse.

Since claims 1, 3-14, 16, 17, and 40-60 have been cancelled, the rejection of these claims is moot. With respect to amended claim 39 and the newly added claims, Applicants submits that none of the allegedly conflicting claims have issued and therefore respectfully requests that the rejections be withdrawn and that the rejections not be applied to the newly-presented or amended claims.

Claim Rejections under 35 U.S.C. § 112

1. Rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 3-14, 16, 17, and 39-60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

In the first part of the rejection under 35 U.S.C. § 112, the Examiner states that all claims include a limitation of a dosage of x mg/kg and that it is unclear what the kg refers to. Applicants respectfully traverse. Applicants contend that it would be understood by one skilled in the art that the kg refers to kg of the individual to which the dsDNA epitope is administered. Since claims 1, 3-14, 16, 17, and 40-60 are cancelled, however, the rejection of these claims is moot. Claim 39, as amended, no longer recites "mg/kg." In addition, none of the newly added claims recite "mg/kg." New claim 72 explicitly recites "about 5 mg to about 100 mg of the conjugate per kg of the individual."

The second part of the rejection under 35 U.S.C. § 112 relates only to claim 1 and 47. Both claims have been cancelled by virtue of this amendment, thereby rendering this rejection moot.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn, and that the rejection not be applied to the newly added or amended claims.

2. Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 3-14, 16, 17, and 39-60 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner alleges that the specification and the claims as originally filed do not provide support for the invention as now claimed. Applicants respectfully traverse.

(a) "for at least about one month" (claims 1, 39, 40, 45, 55, and 60) and "dose of about 3 mg/kg or higher" (claims 1, 39, 40, and 55)

Claims 1, 40, 45, 55, and 60 have been cancelled, without prejudice, by virtue of this amendment. Accordingly, the rejection of these claims is moot.

Claim 39 has been amended to no longer recite "3 mg/kg or higher," but continues to state that the sustained reduction in the level of circulating anti-dsDNA antibodies in the individual is maintained "for at least about one month."

Support for the addition of "for at least about one month" in the previously filed Amendment is found, e.g., in lines 1-13 of paragraph [0084] at page 26 and in lines 14-16 of paragraph [0134] at page 45.

In light of the foregoing remarks, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn, and that the rejection not be applied to the newly added or amended claims.

(b) "dose of about 5mg/kg to about 100 mg/kg" (claims 41, 53, and 56)

The Examiner has asserted that the specific dosage "a dose of about 5 mg/kg to about 100 mg/kg" in claims 41, 53, and 56 is not disclosed in paragraph [0219]. Applicants respectfully traverse this rejection.

Claims 41, 53, and 56 have been cancelled, without prejudice, by virtue of this amendment. Accordingly, the rejection of these claims is moot. However, new claim 72 reads "dose of about 5 mg to about 100 mg of the conjugate per kg of the individual." Applicants will therefore focus their arguments for adequate written description on claim 72.

It is well established that to meet the written description requirement, an applicant's specification must "convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath, Inc. v. Marhurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). This is the standard that the Federal Circuit has set. Literal support is not a requirement. With respect to numerical ranges in particular, MPEP 2163.05 states, "With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." ... however a limitation to "between 35% and 60%" did meet the description requirement." Thus, in *In re Wertheim*, the description of a range and two values within the range was found to sufficiently disclose a new, narrower range within the described range.

Applicants contend that based on paragraph [0219] one of ordinary skill in the art would recognize the inventors to be in possession of the method of claim 72 involving a "dose of about 5 mg to about 100 mg of the conjugate per kg of the individual," and, therefore, the written description requirement is met. Applicants contend that the facts in the present case are largely analogous to the facts in *In re Wertheim* as summarized in MPEP 2163.05 and outlined above.

Lines 10-13 of paragraph [0219] of the present application read, "Generally, a dose of about 1 μg to about 100 mg conjugate/kg body weight, preferably about 100 μg to about 10 mg/kg body weight, preferably about 150 μg to about 5 mg/kg body weight, preferably about 250 μg to about 1 mg conjugate/kg body weight." Thus, the specification in paragraph [0219] provides the dose range of "about 1 μg to about 100 mg conjugate/kg body weight." Since the specification in paragraph [0219] also states "about 150 μg to about 5 mg/kg" and "about 100 μg to about 10 mg/kg," doses of "about 5 mg/kg" and "about 10 mg/kg" are clearly described. The described dose amounts "about 5 mg/kg" and "about "10 mg/kg" are values within the described dose range of "about 1 μg to about 100 mg conjugate/kg body weight." and, therefore, the narrower dose range of "about 5 mg/kg to about 100 mg of the conjugate per kg" is also fully disclosed.

In light of the foregoing remarks, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn, and that the rejection not be applied to the newly added or amended claims.

(c) "dose of about 10 mg/kg or higher" (42, 54, and 57)

Claims 42, 54, and 57 have been cancelled, without prejudice, by virtue of this amendment. Accordingly, the rejection of these claims is moot.

In light of the foregoing remarks, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn, and that the rejection not be applied to the newly added or amended claims.

(d) "dose of about 200 mg to about 500 mg" (claim 58)

The Examiner has asserted that "a dose of about 200 mg to about 500 mg" in claim 58 is not disclosed in paragraph [0219]. Applicants respectfully traverse this rejection.

Claim 58 has been cancelled, without prejudice, by virtue of this amendment. Accordingly, the rejection of claim 58 is moot. However, new claim 73 reads "dose of about 200 mg to about 500 mg." Applicants will therefore focus the arguments for adequate written description on claim 73.

As stated above, it is well established that to meet the written description requirement, an applicant's specification must "convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath, Inc. v. Marhurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). This is the standard that the Federal Circuit has set. Literal support is not a requirement.

Applicants contend that based on paragraph [0219] one of ordinary skill in the art would recognize the inventors to be in possession of a "dose of about 200 mg to about 500 mg" as recited in claim 73, and therefore, the written description requirement is met. Lines 16-18 of paragraph [0219] of the present application read, "Other dosages, such as about 50 to 100 mg per week, 50 to 250 mg per week, and 50 to 500 mg per week (with any value inbetween the lower and upper limit of these ranges) are also contemplated." Since the specification clearly states "with any value inbetween the lower and upper limit of the ranges," the specification discloses all doses between about 50 mg and about 500 mg, including those doses between "about 200 to about 500 mg."

In light of the foregoing remarks, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn, and that the rejection not be applied to the newly added or amended claims.

(e) "dose of about 300 mg" (claim 59)

Claim 59 has been cancelled, without prejudice, by virtue of this amendment. Accordingly, the rejection of this claim is moot.

In light of the foregoing remarks, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn, and that the rejection not be applied to the newly added or amended claims.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 252312007900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 14, 2008

Respectfully submitted,

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